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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,144	09/23/2003	Esko Alanen	881B.0006.U1(US)	1370

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EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/670,144

Applicant(s)

ALANEN ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is responsive to the amendment filed 1/25/2007. Claims 1, 4-7, and 10 are amended. Claim 11 is new. **Claims 1-11** are pending.

Priority

2. Receipt is acknowledged of Finnish application 20010601 filed 3/23/2001 submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Additionally, it is noted that PCT/FI02/00234 filed 3/21/2002, which depends upon the above foreign application, still has not been received.

Claim Objections

3. **Claims 1-6 and 11** are objected to because of the following informalities:

Regarding **Claim 1**, it is unclear what is recited in the claim because both a broad limitation of "electromagnetic probe" as well as a narrow limitation of "open-ended coaxial cable" is claimed at the same time. Applicant is suggested to amend the claim to reflect a consistent claim interpretation.

Regarding **Claims 5-6**, the recited "the electric field" lacks antecedent basis as not having been introduced in any prior claims.

Regarding **Claim 11**, the term "the probe" recited in the step "transmitting a first portion of the signal of the first signal to *the probe*" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-2 and 4-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al (US Pat No. 6370426) in view of Malicki et al (US Pat No. 4918375), further in view of Zhao (US Pat No. 5833686).

6. Campbell discloses a method for measuring edema which is defined as fluid in the interstices of cells in tissue spaces or skin water content comprising an electromagnetic probe placed on the skin during the measurement and the capacitance of the probe or open-ended coaxial cable is measured to measure the skin water content or edema, best seen in Figure 1 (Col.4: 49-65).

However, Campbell et al do not disclose the capacitance of the probe as proportional to the dielectric constant of the skin and subcutaneous fat issue and proportional to the water content of the skin, and is silent to the frequency used.

7. Malicki et al teach that there is a direct known relationship between the dielectric constant of a material and its water content for capillary-porous materials (abst, col. 1 line 10-18). Zhao teaches that it is known to use a frequency of about 50 MHz to effectively treat many skin conditions as such frequency will penetrate skin without side effects (abst).

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8. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Campbell et al such that the capacitance of the probe is proportional to the dielectric constant of the skin and the subcutaneous fat tissue, which is further proportional to the water content of the skin, as taught by Malicki et al, wherein it is known to one of ordinary skill in the art that subcutaneous fat tissue has a low dielectric constant and thus does not affect the water content, due to the known relationship between said elements for capillary-porous materials, which include skin, to give rise to an effective method for measuring tissue edema.

9. Therefore, it would have also been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Campbell et al as modified by Malicki et al such that a frequency of 50 MHz is used to determine edema, as taught by Zhao, because such frequency is effective for penetrating skin and treating skin conditions, such as tissue edema or skin water content.

10. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al in view of Malicki et al, further in view of Zhao, and even further in view of Sherwin (US Pat No. 4640290). Campbell et al in combination with Malicki et al and Zhao disclose the method described above but do not teach the probe secured to the skin by an attachment such as a strap for continuous edema monitoring. Sherwin teaches using straps as an effective method of attaching a probe to the body of a patient (Col.4, line 15-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Campbell et al as modified by

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Malicki et al and Zhao to use a strap attachment, as taught by Sherwin, to aid in securing the probe to the skin for continuous monitoring.

11. **Claims 7-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al in view of Amerena (US Pat No. 4860753), further in view of Zhao.

12. Campbell et al disclose a device capable of measuring tissue edema or skin water content comprising an electromagnetic probe placed on the skin during the measurement, wherein the capacitance of the probe is capable of being proportional to the dielectric constant of the skin and the subcutaneous fat tissue, which is further proportional to the water content of the skin and includes a frequency unit (53) for measuring the capacitance of the probe and a unit (75) for calculating measured values and the edema or skin water content, best seen in Figure 1 (Col.4: 49-65; Col.5: 43-47). However, Campbell et al is silent as to the frequency used as well as to the distance between the two electrodes of the probe.

13. Amerena discloses probe used to measure the water content of skin comprising two concentric electrodes spaced in the range of 2-10 mm as an effective device for such purpose, best seen in Figure 2 (Col.2, line 42-45, abst). Zhao teaches that it is known to use a frequency of about 50 MHz to effectively treat many skin conditions as such frequency will penetrate skin without side effects (abst).

14. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Campbell et al so that the two

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electrodes have a distance of 2-10 mm between, as taught by Amerena, as an effective method and apparatus for measuring tissue edema.

15. Therefore, it would have also been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Campbell et al as modified by Amerena such that a frequency of 50 MHz is used to determine edema, as taught by Zhao, because such frequency is effective for penetrating skin and treating skin conditions, such as tissue edema or skin water content.

16. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Malicki et al in view of Amerena or Campbell et al.

17. Malicki et al disclose a method of measuring substrate moisture comprising:

placing a coaxial electrode on a substrate (Col.2: 12-18);

generating a first signal from an oscillator (Col.2: 18-20), wherein the frequency of the first signal is about 20 to 500 MHz (Col.1: 45-46);

transmitting a first portion of the signal of the first signal to the probe and through the substrate (Col.2: 21-24);

receiving a reflected signal from the substrate through the probe (Col.2: 29-31);

leading the reflected signal to a first input of a phase detector;

transmitting a second portion of the first signal to a second input of the phase detector (Col.2: 24-29);

operating the phase detector in a saturated state, wherein signal amplitudes from the reflected signal and the second portion of the first signal form the saturated state;

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measuring the phase difference, i.e. time delay, between the reflected signal and the second portion of the signal (Col.2: 31-34);

calculating a dielectric constant from the phase difference (Col.2: 35);

calculating a water content of the substrate based on the dielectric constant (Col.2: 36).

18. However, Malicki et al do not disclose said method used for measuring a water content of the skin such that said probe is placed on the skin during use. Amerena or Campbell et al teach an analogous signal generating method used to measure a water content of the skin wherein a coaxial electrode is placed on the skin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the method of Malicki et al to measure the water content of the skin as taught by Amerena or Campbell et al, wherein in use the coaxial electrode is placed on the skin and the frequency of the signal used will penetrate the skin and subcutaneous fat tissue, as an obvious useful application of the method to a capillary-porous material as taught by Malicki et al (Col.1: 6-7).

Response to Arguments

19. Regarding the use of Malicki et al, applicant contends that said reference discloses a dielectric method that is not applicable for skin or tissue measurements because the probe dimensions are too large. This is not found persuasive because Malicki et al disclose a general dielectric method for all capillary-porous materials (Col.1: 1-2), which includes skin, as well as other specific applications. Furthermore, applicant has not specified the exact dimensions required for the invention above and

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thus Malicki et al in combination with the references above provide a proper §103 rejection as motivated by the reasons explained above.

20. Regarding the use of Amerena, applicant contends that there is no teaching of detecting the moisture content of deeper skin structures within the dermis such as the underlying subcutaneous fat tissue and that the proper frequency range is not disclosed. However, the examiner notes that the said claims do not recite measuring the moisture content of subcutaneous fat tissue but rather measurement of tissue edema, which is defined as fluid in the interstices of cells in tissue spaces and wherein skin water content constitutes such as described above. Furthermore, the examiner notes that Amerena has not been referred to for the teaching of the desired frequency range.

21. Finally, regarding the use of Zhao, applicant contends that the reference does not teach an apparatus having the function or capability to measure tissue edema and that there is not disclosure of the effective depth of the treatment. The examiner notes that once again, Zhao is merely used to teach the desired frequency range for use on skin as motivated by the reasons discussed above and furthermore, the use of the desired frequency range necessitates that said energy penetrate the desired depth as even recited in claims 5-6.

22. Additionally, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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23. Applicant also purports that proper motivation is lacking for said combinations. However the examiner notes that proper motivation has been provided as elaborated above. Furthermore, applicant has also disclosed in the specification that at least certain aspects of the invention are known in the art (p.5 line 15).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

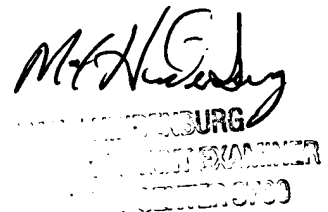
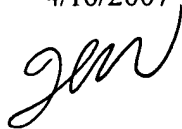
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN

4/16/2007



MAX HINDENBURG
PATENT EXAMINER
ART UNIT 3736